K01 1604

AUG 2 2 2001

GE Medical Systems

PO Box 414, W-709
Milwaukee, WI 53201
USA

SUMMARY OF SAFETY AND EFFECTIVENESS

- This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87(h).

- Identification of Submitter
  Larry A. Kroger, Ph.D., 262-544-3894

- Identification of the Product
  PROstate **S**pectroscopy and imaging **E**xam (PROSE) software option

  Manufactured by: GE Medical Systems
  3200 N. Grandview Blvd.
  Waukesha, WI 53188

- Device Description

  PROSE is a version of the PRESS (Point RESolved Spectroscopy), "double" spin echo pulse sequence that uses a 90° and two slice selective refocusing RF pulses to generate a spin echo from a localized volume. PROSE utilizes the standard Graphic Prescription tools and one or more sets of localizer images to determine the size and location of the spectroscopic volume.

- Indications for Use

  PROstate **S**pectroscopy and imaging **E**xam (PROSE) is an image guided, clinical imaging and spectroscopy package which acquires high resolution anatomical images and volume localized, water/lipid suppressed hydrogen spectra and/or multi-voxel spectroscopic images of the prostate gland using an endo-rectal coil with phased-array coils. PROSE option can be used in conjunction with a Magnetic Resonance Scanner to permit non-invasive acquisition of high resolution images and spectral information about relative concentrations of metabolites of prostate gland that can be interpreted by a trained physician, and yield information that may assist in diagnosis of prostate diseases.

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- Comparison with Predicate

The Prostate Spectroscopy and Imaging Exam (PROSE) software option is substantially equivalent to existing scanning, processing and display features included with the GE Medical Systems PROBE software option (K930265). The PROBE software is modified to deliver improved spatial coverage through the PRESS volume and extend the use of the PROBE sequence for the Prostate Gland. PROBE is largely limited to the Brain.

- Summary of Studies

The Prostate Spectroscopy and Imaging Exam (PROSE) software option was evaluated to the IEC 601-2-33 International medical equipment safety standard for Magnetic Resonance Systems. Evaluation testing was done to verify the performance of the option in the clinical environment.

- Conclusions

It is the opinion of GE Medical Systems that the Prostate Spectroscopy and Imaging Exam (PROSE) software option does not result in any new potential hazards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 2 2001

Larry A. Kroger, Ph.D.
Senior Regulatory Programs Manager
GE Medical Systems
P.O. Box 414, W-709
MILWAUKEE WI 53201

Re: K011604
Prostate Spectroscopy and Imaging Exam (PROSE)
(Magnetic Resonance Diagnostic System)
Dated: May 23, 2001
Received: May 24, 2001
Regulatory Class: II
21 CFR 892.1000/Procode: 90 LNI

Dear Dr. Kroger:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K01 1604

Device Name: **PRO**state Spectroscopy and imaging Exam (PROSE) Package for GE Signa Magnetic Resonance Scanners

Indications For Use:

PROstate Spectroscopy and imaging **E**xam (PROSE) is an image guided, clinical imaging and spectroscopy package which acquires high resolution anatomical images and volume localized, water/lipid suppressed hydrogen spectra and/or multi-voxel spectroscopic images of the prostate gland using an endo-rectal coil with phased-array coils. PROSE option can be used in conjunction with a Magnetic Resonance Scanner to permit non-invasive acquisition of high resolution images and spectral information about relative concentrations of metabolites of prostate gland that can be interpreted by a trained physician, and yield information that may assist in diagnosis of prostate diseases.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K011604

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)